DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
New Orleans District
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

July 29, 2003

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Nancy E. Eckert
President and CEO
LifeSouth Community Blood Centers
1221 NW 13th Street
Gainesville, Florida 32601

Warning Letter No. 03-NSV-20

Dear Ms. Eckert:

On March 12-21, and April 2-7, 2003, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 1601 Eastern Boulevard, Montgomery, Alabama. Our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, *Code of Federal Regulations* (21 CFR), Parts 211, 600-680 as follows:

- You failed to permanently defer a donor who tested Rapid Plasma Reagin (RPR) reactive as required in your written procedures. [21 CFR 606.165(e)]

- You failed to file Biological Product Deviation Reports on three units which represented a storage temperature deviation and two communicable disease hazards. [21 CFR 606.171(b)]

- You erroneously labeled and distributed three double platelet apheresis products as leukoreduced and six leukoreduced platelet apheresis products as standard leukoreduced products, when these products failed to meet their respective specified standards. [21 CFR 606.120(b)(3)]

- You failed to maintain written standard operating procedures (SOPs) for the following:

  - To require the investigation of products that fail leukoreduction or fail to meet minimum platelet counts during routine sampling. [21 CFR 606.100(b)]

- You failed to specify the type of storage container to be used to store third part, part 12780 LPR3, when a third product is collected. [21 CFR 606.100(b)]

- You failed to specify the time limit for welding the third platelet storage container used in collecting triple products. [21 CFR 606.100(b)(6)]

- You failed to perform an investigation for nine products that failed leukoreduction and two products that failed to meet the minimum platelet counts during routine sampling. [21 CFR 606.100(c), 21 CFR 211.92, and 21 CFR 640.25(b)(4)]

- Many of the records intended to document the control of critical operations at your firm are not adequately maintained or reviewed as required. These records include but are not limited to donor flowsheets, Apheresis Instrument Alarm and Reaction Tracking Records, Apheresis Instrument Exception Logs, Separator Instrument Maintenance Records, Instrument Daily Maintenance Logs, Apheresis Records, Sterile Device Docking Records, and Apheresis Donor History Records. [21 CFR 606.160, 21 CFR 211.100, 21 CFR 211.192(a), 21 CFR 211.68(a), and 21 CFR 211.22(a)]

  - There was no record of welding a storage bag to a collection set on one occasion. [21 CFR 606.160]

  - Informed consents were often missing or misplaced, not dated, or not dated correctly. [21 CFR 606.160(b)(1)(i) and 21 CFR 211.100(b)]

  - Donor flow sheets were often missing or misplaced, which contributed to at least two instances where donors donated in less than 28 day interval; a donor was allowed to donate even though their platelet count was unacceptable; and donations for three donors were not recorded because the donor history records were not available at the time of the donation. [21 CFR 606.160 and 21 CFR 211.100(a)]

  - Therapeutic Concentrate Platelets (TCP) sample collection documentation was frequently missing, or incomplete. [21 CFR 606.160 and 21 CFR 211.100(b)]

  - There were numerous instances where the activation of instrument alarms was not properly recorded as per your SOPs. [21 CFR 606.160(b)(7)(iv)]

- You failed to document the approval of the Operation Qualification Protocol and the Performance Qualification Protocol for the [redacted]. The instrument is in use without the validation being complete. [21 CFR 211.68(a)]

This letter is not intended to be an all-inclusive list of deficiencies noted at your Montgomery facility. It remains your responsibility as the Responsible Official to assure that your establishment is in compliance with all requirements of the federal regulations.

We acknowledge receipt of correspondence dated April 28, 2003 from Jill Evans, Director of Quality Assurance, on your behalf. This correspondence responds to the Form FDA 483 issued to L. Dewayne Defee, Branch Manager of the Montgomery facility at the conclusion of the inspection. Your response fails to demonstrate to us your recognition of the seriousness of your quality control system failures. Your investigative efforts and the source of these failures are not readily apparent in your response. Only a future re-inspection can evaluate the adequacy and permanence of your stated changes and corrections.

If you care to respond further to these matters, please do so to the attention of Kari L. Batey, Compliance Officer, at the above letterhead address. Failure to promptly and effectively correct the conditions and practices noted at this facility, could result in regulatory action without further notice. Such action includes license suspension and/or revocation, seizure and/or injunction.

Sincerely,

Carl E. Draper
Director, New Orleans District

CED:klb

Enclosures:
- FDA 483 issued on 4/7/03
- Copy of 4/28/03 Evans letter

cc: Judy Russell
Regional Director
LifeSouth Community Blood Centers
Montgomery Region
1601 Eastern Boulevard
Montgomery, AL 36117-1607

L. Dewayne Defee
Branch Director
LifeSouth Community Blood Centers
Montgomery Region
1601 Eastern Boulevard
Montgomery, AL 36117-1607